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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,455	06/23/2003	Rosenberg Meir	COD5001USNP	9738

27777 7590 07/21/2010

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ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
07/21/2010	ELECTRONIC

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/601,455
Filing Date: June 23, 2003
Appellant(s): MEIR, ROSENBERG

Eugene L. Szczecina, Jr.
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1 June 2010 appealing from the Office action mailed 16 November 2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: 1-41 and 43-46

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,585,677	COWAN, Jr	07-2003
6,248,080	MIESEL et al	06-2001
4,206,762	COSMAN	06-1980
7,371,223	COUVILLON, Jr. et al	05-2008
2003/0004495	SAUL	01-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-24, 38-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al, further in view of US 7,371,223 to Couvillon, Jr. et al.

In the specification and figures, Cowan discloses the device substantially as claimed by applicant. With regard to claims 1, 18, 19, 40, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the housing, a pressure sensor or valve-gauge assembly 52 disposed within the housing downstream of the valve, and a CPU or microprocessor associated with element 52 disposed within the housing and connected to the valve-gauge assembly 52. Cowan discloses that valve-gauge assembly 52 comprises a pressure sensor (indicating it is contained within housing 24) *and* a ventricular pressure gauge 52 (see FIG 1, columns 3-4, column 5, lines 11-20). Accordingly, Cowan teaches a valve and pressure sensor (valve-gauge assembly 52) disposed within the housing 24 downstream of valve 50.

Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that

allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance.

Cowan and Miesel fail to disclose that the pressure sensors and controllers are non-invasively wirelessly powered. However, Couvillon discloses an implantable fluid control device that may use waveform data sent to a receiver that powers an implanted component in order to reduce the size of the control unit (see column 12, lines 28-39). It would have been obvious to one having ordinary skill in the art at the time of invention to use wireless, non-invasive power, such as that disclosed by Couvillon, to supply power to the apparatus suggested by Cowan and Miesel in order to reduce the size of the controller, as taught by Couvillon.

With regard to claims 2-3, 9, the CPU or valve-gauge assembly with processing unit 52 disclosed by Cowan is electrically connected to the pressure sensors (see columns 5-6, FIG 1). The valve-gauge assembly is connected to transmitter 64 that transmits information to an external computing device (see column 6, lines 1-15).

With regard to claims 4, 5, 10, and 14, applicant claims that the CPU comprises a "means for calculating" a particular parameter. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

a. the claim limitations must use the phrase "means for " or "step for; "

b. the "means for " or "step for " must be modified by functional language; and

c. the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant has satisfied all three prongs of the test and the Examiner has turned to the specification for clarification.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure... described in the specification and equivalents thereof." See MPEP 2181(II). In paragraph 0008 of US 2004/0260229, applicant discloses that the CPU compares values generated by the pressure sensors to generate a differential pressure. It is the position of the Examiner that this disclosure indicates that the "means for calculating" comprises a programmed algorithm. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26). Such programs are considered by the Examiner to be functional equivalents of the algorithm disclosed by applicant, since differential pressure values are known in the art to control valve movement. Accordingly, the disclosure of Cowan suggests the apparatus of applicant's claims 4, 5, 10, and 14.

With regard to claims 6-8, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claim 20, Cowan and Meisel fail to disclose that the CPU is located outside the housing 24. It has been held that mere rearrangement of the parts of a device found in the prior art is within the skill of a worker in the art, especially if the

device with the instantly claimed arrangement would not perform differently than the prior art device. See MPEP 2144.04(IV)(B). In the instant case, applicant has not stated that the location of the CPU outside the housing is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the CPU does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

With regard to claims 21, 24, 38, and 39, Cowan discloses a first pressure sensor 54 upstream of the valve 50. Cowan also discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52 (contained entirely within the housing), 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a pressure sensor upstream of the valve within the housing. However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that

allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement 52 downstream of the valve as disclosed by Cowan to a location upstream of the valve 50 in order to diagnose valve performance using the programmed CPU and wireless communication disclosed by Cowan.

With regard to claims 22-23, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressures sensors 52, 54 and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). Cowan fails to disclose a fourth pressure sensor on second catheter 32. However, However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and

treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in order to diagnose blockages throughout the system.

With regard to claims 41, 43, 44 and 46, Cowan and Miesel suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 6,248,080 to Miesel et al, in view of US 7,371,223 to Couvillon, Jr. et al, further in view of US 2003/0004495 to Saul et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claims 15-17, applicant claims that the CPU "is powered" by a particular technology. Such limitations set forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a

claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Applicant provides no structural limitation that allows for such diverse power methods. However, the cited prior art does not suggest that it may be powered in such a fashion. Saul discloses a fluid management apparatus that uses RF energy, optical energy, "or the like," which may include acoustic energy, to power a battery connected to a valve. It has been held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007). In the instant case, it is the position of the Examiner that since all the claimed elements are known in the art, it would have been obvious to one having ordinary skill in the art at the time of invention to add the external power sources disclosed by Saul to the fluid management apparatus suggested by the cited prior art, yielding only the predictable result of an implantable fluid management device that may be powered by wireless sources.

Claims 25-30, 37, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, further in view of US 7,371,223 to Couvillon, Jr. et al.

In the specification and figures, Cowan discloses the apparatus and method substantially as claimed by applicant. With regard to claim 25, Cowan discloses an implantable medical device 20 comprising a housing 24, valve 50 disposed within the

housing, a pressure sensor 52 disposed within the housing downstream of the valve, and a microprocessor associated with element 52 disposed within the housing and connected to the pressure sensor (see FIG 1, columns 3-4).

Cowan fails to disclose that the pressure sensor 52 comprises a differential pressure sensor. However, Cosman discloses an implantable differential pressure sensor that upon undergoing a conformational change, transmits that information to an external device. The device allows for the accurate measurement of a difference in pressure across a membrane (see columns 1-2). The combination of the shunt apparatus disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

Cowan and Cosman fail to disclose that the pressure sensors and controllers are non-invasively wirelessly powered. However, Couvillon discloses an implantable fluid control device that may use waveform data sent to a receiver that powers an implanted component in order to reduce the size of the control unit (see column 12, lines 28-39). It would have been obvious to one having ordinary skill in the art at the time of invention to use wireless, non-invasive power, such as that disclosed by Couvillon, to supply power to the apparatus suggested by Cowan and Cosman in order to reduce the size of the controller, as taught by Couvillon.

With regard to claim 26, both Cowan and Cosman disclose that the apparatus is connected to an apparatus that transmits information to an external computing device (see Cowan column 6, lines 1-15, Cosman column 1, lines 13-24).

With regard to claims 27-30, Cowan discloses a first catheter 28 fluidly connected to housing 24 upstream of valve 50 with a pressure sensor 54 disposed within the catheter 34 and connected to the CPU or valve-gauge assembly 52 (see FIG 1).

With regard to claim 37, Cowan discloses that the valve-gauge assembly 52 comprises a microprocessor that receives input from the pressure sensors and is programmed with various criteria to determine whether the valve should be opened or closed (see column 5, lines 11-26) and may wirelessly transmit data to an external device (see column 6, lines 1-15). The combination of the method disclosed by Cowan with the differential pressure sensor disclosed by Cosman by known methods yields only predictable results—that is, a shunt system and method that relies on a single sensor, rather than two sensors, to generate a differential pressure measurement to operate an associated shunt valve. Accordingly, it is the position of the Examiner that taken together, the references reasonably suggest the claimed invention to a person of ordinary skill in the art.

With regard to claim 45, Cowan and Cosman suggest the apparatus as claimed with the exception of the components disposed on the same substrate. Applicant has not shown that the location of the components on the same substrate is for any particular purpose or solves any particular problem. It is the position of the Examiner

that the location of the components on the same substrate does not affect the performance of the device either as suggested by the prior art or as claimed by applicant. Accordingly, the claimed apparatus is unpatentable over the prior art of record.

Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, in view of US 7,371,223 to Couvillon, Jr. et al, further in view of US 2003/0004495 to Saul et al.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by Applicant (see rejection above).

With regard to claims 34-36, applicant claims that the CPU "is powered" by a particular technology. Such limitations set forth the intended use of the claimed apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, Applicant provides no structural limitation that allows for such diverse power methods. However, the cited prior art does not suggest that it may be powered in such a fashion. Saul discloses a fluid management apparatus that uses RF energy, optical energy, "or the like," which may include acoustic energy, to power a battery connected to a valve. It has been held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct.

1727, 1739 (2007). In the instant case, it is the position of the Examiner that since all the claimed elements are known in the art, it would have been obvious to one having ordinary skill in the art at the time of invention to add the external power sources disclosed by Saul to the fluid management apparatus suggested by the cited prior art, yielding only the predictable result of an implantable fluid management device that may be powered by wireless sources.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al in view of US 4,206,762 to Cosman, in view of US 7,731,223 to Couvillon, Jr. et al, further in view of US 6,428,080 to Miesel.

In the specification and figures, the cited prior art suggests the apparatus substantially as claimed by applicant (see rejection above) with the exception of an additional pressure sensor located on a second catheter. With regard to claims 11-13, Cowan discloses a catheter 32 fluidly connected to housing 24 downstream of valve 50. Cowan fails to disclose a fourth pressure sensor on second catheter 32.

However, Miesel discloses an intracranial monitoring and therapy control device that may comprise several pressure sensors in and around a treatment device such as a valve in order to permit more accurate treatment of cerebral symptoms in a patient (see column 9, lines 20-67, column 11, lines 40-65). With that disclosure, Miesel suggests the addition of multiple pressure sensors around a treatment device in order to diagnose problems in the treatment apparatus, such as a catheter or valve blockage. Taken together, the references reasonably suggest to one of ordinary skill in the art an

implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to merely duplicate the pressure sensor arrangement on the first catheter 28 disclosed by Cowan on the second catheter 32 in the apparatus suggested by Cowan and Cosman in order to diagnose blockages throughout the system.

(10) Response to Argument

Applicant argues that Couvillon does not disclose an implant that is wirelessly powered since Couvillon discloses that the control unit 150 comprises a battery as a source of power. However, the Examiner notes that Couvillon discloses that "depending on the procedure time…a battery **can** be used as a source for power" (Column 12, lines 53-55, emphasis added). Such a disclosure indicates that a battery may be used, but certainly does not require a battery but rather that a battery is but one type of power source and in fact by such statement teaches the antithesis that a battery is required. As such, it is the position of the Examiner that Couvillon does not require a battery to power the control unit 150.

Applicant further argues that Couvillon only teaches sending of control data over a wireless communications interface, pointing to column 12, lines 28-30 of Couvillon. The Examiner submits that the cited passage "the received waveform data can then be routed to drivers, which power the actuators within the pump" specifically supports the

Examiner's position—the waveform data moves wirelessly from a transmitter to an implanted receiver that sends the signals to drivers that then provide power to the pumps.

Applicant further argues that Couvillon teaches away from wirelessly powering the device since Couvillon specifically discloses that the control unit comprises a power source 150 that may comprise a battery. Couvillon's disclosure in column 12, lines 28-39, though vague, does not rule out the possibility of the control unit being powered from an outside source. Furthermore, Couvillon discloses that the control unit 150 is provided with its own source of internal power in *an embodiment* of the invention (see column 12, lines 40-42). Not every embodiment requires the controller to have its own source of power.

As such, it is the position of the Examiner that Couvillon discloses the use of a wireless signal to power an implanted component (such as the pumps). One of ordinary skill in the art would be motivated to use a wireless means to power the implanted device, including pressure sensors and CPU, in order to reduce the size of the implant, as taught by Couvillon. As such, it is the position of the Examiner that the Couvillon disclosure, along with the other cited prior art, suggests the limitations of the claimed invention.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Leslie R. Deak/

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/Eric Nicholson/
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Supervisory Patent Examiner, Art Unit 3761